

REMARKS

This responds to the Office Action dated February 12, 2007. Claims 1, 18, 19, and 43 are amended. No claims are cancelled or added. As a result, claims 1-48 remain pending in this Office Action.

§102 Rejection of the Claims

Claims 1-6 and 16-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by Siegel (U.S. Patent No. 5,062,841). Applicant respectfully traverses this rejection.

Applicant cannot find in the cited portions of Siegel any disclosure of a biocompatible body having a portion that changes in response to a physiological condition “when that portion of the body is in contact with the tissue” and “wherein the change in the at least one physical property occurs because of the contact between that portion and the tissue” and “wherein the at least a portion of the body is sized and shaped such that the change in the physical property is detectable using acoustic energy,” as presently similarly recited or incorporated in claims 1-6 and 16-17.

Instead, Siegel apparently merely discloses a glucose sensitive water-swallowable hydrogel member located within a housing 1, with Siegel’s device configured such that a difference in pressure between the inside of Siegel’s housing 1 and the patient’s body causes insulin to be pushed out from the housing 1 and into the body of the patient. (*See, e.g.*, Siegel column 4 lines 29-35). Because Siegel’s water-swallowable member is located within a housing, it necessarily cannot contact tissue, as similarly presently recited or incorporated in claims 1-6 and 16-17. Because Siegel does not disclose all elements presently recited or incorporated in claims 1-6 and 16-17, Applicant respectfully submits that no *prima facie* case of anticipation presently exists with respect to such claims.

Moreover, Siegel utterly fails to disclose that its swallowable member changes to an extent such that it is capable of being detected by acoustic energy. Instead, the Office Action states:

Examiner takes the position that change in size due to swelling, is inherently detectable by the use of acoustic energy.

(Final Office Action ¶ 2.) The Office Action failed to provide any reasoning for this assertion of inherency, and Appellant respectfully disagrees with this assertion. Appellant respectfully

submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). First, nothing in Siegel explains how its swellable member will change to an extent that would be capable of being detected by acoustic energy with adequate signal-to-noise ratio to discern such a change. Second, Applicant respectfully submits that it is not at all apparent that Siegel's swellable member could be detected by an acoustic energy source because Siegel's swellable member is located inside of a housing 1. Siegel further discloses that such housing is rigid:

A cylindrical housing 5 cm in length with a circular internal base area of 2 cm² is prepared from a suitable rigid material such as polymethylmethacrylate.

(Siegel at col. 12, lines 65-67.) Applicant respectfully submits that the rigid housing 1 of Siegel will inhibit transmission of acoustic energy to the swellable member, and Siegel certainly has not disclosed using an ultrasound source located within the housing 1 to detect a change in size of the swellable member. Moreover, because Siegel's swellable member is within a housing 1, it is necessarily not in contact with tissue as recited or incorporated in the present claims. The Final Office Action responded to Applicant's previous similar remarks by stating:

Applicant argues that Siegel fails to disclose that the swellable member changes to an extent such that it is capable of being detected by acoustic energy. [The Examiner] maintains the position that the change in size due to swelling will inherently be detectable by the use of acoustic energy, such as medical ultrasound in the range of 10-15MHz which provides high axial and lateral resolution. It is also a reasonable assertion that ultrasound will be able to detect such changes through a housing.

(Final Office Action ¶ 7.) Applicant very respectfully submits that there is no objective evidence of record for the proposition that "ultrasound will be able to detect such changes through a housing." To the extent that the Office Action is relying on Official Notice, Applicant timely objects and requests that—as expressly required by MPEP § 2144.03—the Examiner submit an affidavit, or at least provide an objective reference, showing an example of ultrasound imaging through a rigid polymethylmethacrylate (PMMA) housing that has been implanted within a human or animal subject. Applicant respectfully notes that a rigid PMMA housing will have a

very different acoustic impedance from the surrounding tissue, as well as from the swellable member that it houses according to Siegel. Therefore, Applicant respectfully submits that it is not at all clear from the record that Siegel could function in the manner asserted.

Because Siegel apparently does not expressly or inherently disclose all elements presently recited or incorporated in claims 1-6 and 16-17, Applicant respectfully submits that no *prima facie* case of anticipation presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

Claims 1-33, 35, 36, 38 and 40-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630) in view of Lew et al. (U.S. 2003/0100822) and further in view of Siegel (U.S. Patent No. 5,062,841) as applied above. Applicant respectfully traverses this rejection.

Concerning claims 1-17, 37-39, and 43-48:

Applicant respectfully traverses this rejection on the grounds that no *prima facie* case of obviousness presently exists with respect to these claims, because all elements are not disclosed in Altman, Lew, and/or Siegel for reasons similar to those stated above with respect to the § 102 rejection, and for the reasons discussed in Applicant's previous response, which, for brevity, are incorporated herein by reference.

As discussed above, Siegel fails to disclose, teach, or even suggest body "in contact with tissue" to cause a change in at least one physical property, such change being detectable by ultrasound. Instead, Siegel apparently merely pertains to a glucose monitor having a swellable member contained within a rigid housing, as discussed above. Moreover, Altman is apparently merely directed toward delivering a fluidic anti-arrhythmic agent through a thin hydrogel membrane to a heart wall. (*See* Altman at col. 12, lines 1-17.) Nothing in Altman suggests that its membrane should change at least one physiological property in response to a physiological condition as a result of its contact with tissue, as presently recited or incorporated in these claims. In fact, because Altman's thin membrane is being used for the crucial purpose of regulating delivery of the fluidic anti-arrhythmic agent, Applicant respectfully submits that any such variation as a result of a physiological purpose would interfere with or even destroy this

stated purpose of Altman. Lew apparently is merely directed toward using a hydrogel as a pressure biosensor—but Applicant respectfully submits that nothing in the cited portion of Lew discloses, teaches, or even suggests using ultrasound or other acoustic energy to detect a physiological condition based on an acoustically-detected change in a physical parameter of Lew’s hydrogel. (See Lew ¶¶ 7-9.)

Accordingly, because not all elements recited or incorporated in these claims are not disclosed, taught, or even suggested by Altman, Siegel, and/or Lew, because there is no objective evidence of any motivation to combine these references, and because combining these references would likely inhibit or destroy the stated purpose of Altman, Applicant respectfully submits that there is presently no *prima facie* case of obviousness with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims. For brevity, Applicant defers but reserves the right to present further remarks concerning the dependent claims, which are believed separately patentable.

Concerning claims 18 and 40-42:

Applicant respectfully submits that there is no *prima facie* case of obviousness for this claim for the reasons discussed above. None of Altman, Siegel, or Lew appear to disclose, teach, or even suggest a plurality of spheres that are sized and shaped to be disposed within and to contact a myocardium of a subject, with each sphere including at least one physical property that changes in response to a physiological condition of the subject as a result of the contact with the myocardium. Certainly, Altman’s mesh 85 is not sized and shaped to be disposed “within” a myocardium, but instead is merely sewn onto the surface of the heart. (See Altman at col. 12, lines 1-18.) Similarly, Siegel’s swellable member is not sized and shaped to be located within a myocardium, as it is located within a rigid PMMA housing, as discussed above. Like Altman and Siegel, Lew similarly does not meet this claim language.

Nothing in the cited portions of Altman, Siegel, or Lew discloses using acoustic energy, or an acoustic transmitter or receiver, as recited in claim 18.

Nothing in the cited portions of Altman, Siegel, or Lew discloses using “spheres”, much less spheres that are sized and shaped to be disposed within a myocardium, as recited in claim 18. Although the Office Action contends that a spherical shape would merely be a matter of design choice, Applicant respectfully submits that this choice of shape has patentable

significance in that (1) it allows convenient acoustic detection of a change in size; and (2) it allows convenient bio-friendly implantation into the myocardium.

Accordingly, because not all elements recited or incorporated in these claims are not disclosed, taught, or even suggested by Altman, Siegel, and/or Lew, because there is no objective evidence of any motivation to combine these references, and because combining these references would likely inhibit or destroy the stated purpose of Altman (as discussed above), Applicant respectfully submits that there is presently no *prima facie* case of obviousness with respect to these claims.

Concerning claims 19-36:

For the reasons already discussed above with respect to the § 102 rejection and the § 103 rejection, Applicant cannot find in the cited portions of the cited references any disclosure, teaching, or suggestion of introducing a physiological sensor including at least one body into contact with a tissue, wherein the body includes at least one physiological property that changes as a result of the contact with the tissue in response to a physiological change associated with the tissue, transmitting the acoustic energy to the body and the tissue, receiving transmitted acoustic energy for detecting a change in the physical property of the body, and detecting the physiological change by detecting the change in the physical property of the body, as recited or incorporated in these claims.

For example, the only cited portion of any of Altman, Lew, and/or Siegel that mentions acoustic energy is the following cited passage from Altman:

Other examples include distally located electrically activated piezoelectric crystals or electrodes to act as energy sources for drug delivery for improving the transport into cells, distally located ultrasound transducer for implantation using ultrasound imaging.

(Altman at col. 20, lines 39-43.) Applicant respectfully submits that nothing in this cited passage discloses, teaches, or suggests detecting a physiological change by detecting a change in the physical property of a body introduced into contact with tissue. Instead, the cited passage apparently merely relates to using ultrasonic imaging to help implant an infusion catheter.

Accordingly, because all elements recited or incorporated in these claims are apparently not disclosed, taught, or suggested by Altman, Lew and/or Siegel, Applicant respectfully submits

that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

Allowable Subject Matter

Claims 34, 37, 39, 47 and 48 were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Nonetheless, for the reasons discussed above, Applicant respectfully submits that these claims are allowable in their present form. Accordingly, Applicant respectfully requests allowance of these claims.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

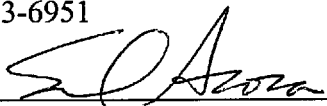
Respectfully submitted,

ROBERT J. SWEENEY ET AL.

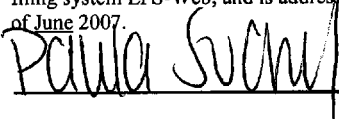
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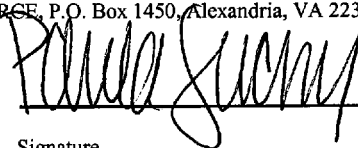
Date June 12, 2007

By 
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Name



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